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PATENT
514413-3834

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : LANDSCHÜTZE
Serial No. : 09/636,289
For : TRANSGENIC PLANT CELLS AND PLANTS HAVING
MODIFIED ACTIVITY OF THE GBSSI AND OF THE BE
PROTEIN
Filed : AUGUST 10, 2000
Examiner : DAVID T. FOX
Art Unit : 1638

745 Fifth Avenue
New York, NY 10151

DECLARATION

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

DR. VOLKER LANDSCHÜTZE, declares and says that:

1. I am the named inventor in the above-captioned application. I have read and I am familiar with the application.
2. My education, training, and experience are as follows. I received my Diploma degree in Biotechnology from the Technische Universität Berlin in 1991 under the supervision of Professor Dr. Lothar Willmitzer. In January 1995, I received my Ph.D. degree from the Technische Universität of Berlin. The work, entitled "Untersuchungen zur Beeinflussung der Acetyl-CoA-Synthese", was carried out at the Institut für

Genbiologische Forschung, under the supervision of Professor Dr. Lothar Willmitzer.

From January 1995 to October 1996, I worked as a post-doctoral fellow at the Institut für Genbiologische Forschung in Berlin, Germany, studying the production and characterization of transgenic plants synthesizing modified starches. Since October 1996, I have been employed at Bayer BioScience, former PlantTec Biotechnologie GmbH. My current function is a Product Research Manager at Bayer. During the last seven-and-a-half years, I worked with, among other things, the analysis and characterization of the properties of modified starches from various sources, especially from transgenic plants. I have been involved in transgenic plant research since 1991. Accordingly, I am considered by my peers to be an expert in the field to which the present application pertains.

3. I am making this Declaration in response to comments raised during the prosecution of this application, regarding whether one skilled in the relevant art to which it pertains, or with which it is most nearly connected, could make and/or use the invention commensurate in scope with the claimed subject matter. Specifically, this Declaration addresses the written description and enablement rejections under 35 U.S.C. §112, first paragraph.

4. It is well known in the art that plants comprise a mechanism of gene silencing known as co-suppression. Co-suppression may occur with ribonucleic acid fragments that are synthesized in the sense orientation. The sequence of the RNA sequences used to facilitate gene silencing need not be identical to its target. Thus, many different and diverse types of RNA sequences may be used, so long as they can hybridize and silence the gene of interest, in this case GBSSI and BE genes. While the instant claims are

directed to the potato, sequences derived from other amylopectin-producing plants such as corn, can be used if sufficient homology exists. The specification supports the use of sequences that exhibit at least 65% homology. It is well within the purview of one skilled in the art to determine the degree of homology and perform sequence alignments of genes of interest spanning different species of plants comprising homologs of the GBSSI and BE proteins using algorithms such as BLAST, available through the National Center for Biotechnology Information at the National Institutes of Health. Further, the breadth of knowledge of the skilled artisan sufficiently permits using and manipulating different RNA sequences to achieve the desired effect, using molecular and cell biological techniques without undue experimentation.

5. Further, sequences may also be selected that do not correlate to a particular gene, wherein gene refers to the coding sequence. Cosuppression has been shown to exist when using sequences corresponding to the untranslated regions of genes involved in modulating expression levels of gene *in vivo*. A short stretch of sequence corresponding to, for example, the untranslated 5' region of GBSSI gene can be used, which does not exhibit homology to the coding sequence of GBSSI, but could be used advantageously to achieve the same effect: decreased expression of GBSSI. The same concept can be applied to BEI proteins as well.

6. In summary, it is my opinion that RNA sequences need not be limited to a specific plant source or a specific gene source, as long as sufficient homology exists to reduce the expression of GBSSI and BEI proteins by gene silencing, which is a well-documented phenomenon that has been studied in detail in plants. Hence, it is clear that gene silencing by antisense or cosuppression technology in plants are not only well-

known technologies to the skilled artisan, but can be successfully applied in the context of the present invention to achieve the claimed effects (decreased activity of GBSSI and BEI proteins).

7. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 10th of March, 2004

By: 
Volker Landschütze